

## PATENT COOPERATION TREATY

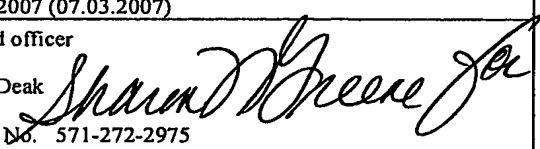
## PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference 53951-137	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416																
International application No. PCT/US04/36933	International filing date (day/month/year) 05 November 2004 (05.11.2004)	Priority date (day/month/year) 07 November 2003 (07.11.2003)																	
International Patent Classification (IPC) or national classification and IPC IPC: A61M 37/00( 2006.01),A61M 1/00 USPC: 604/6.1,6.01,4.01,34,210/424,137/625.43																			
Applicant NXSTAGE MEDICAL, INC.																			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																			
<p>4. This report contains indications relating to the following items:</p> <table border="0"> <tr> <td><input checked="" type="checkbox"/> Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/> Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/> Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/> Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/> Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/> Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/> Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>				<input checked="" type="checkbox"/> Box No. I	Basis of the report	<input type="checkbox"/> Box No. II	Priority	<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/> Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/> Box No. VI	Certain documents cited	<input type="checkbox"/> Box No. VII	Certain defects in the international application	<input type="checkbox"/> Box No. VIII	Certain observations on the international application
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Date of submission of the demand 06 June 2005 (06.06.2005)		Date of completion of this report 07 March 2007 (07.03.2007)																	
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201		Authorized officer Leslie R. Deak Telephone No. 571-272-2975 																	

Form PCT/IPEA/409 (cover sheet)(April 2005)

**Box No. I Basis of the report**1. With regard to the **language**, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☒ the international application as originally filed/furnished
- ☒ the description:  
pages 1-31 as originally filed/furnished  
pages\* NONE received by this Authority on \_\_\_\_\_  
pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ the claims:  
pages 32-37 as originally filed/furnished  
pages\* NONE as amended (together with any statement) under Article 19  
pages\* NONE received by this Authority on \_\_\_\_\_  
pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ the drawings:  
pages 1-15 as originally filed/furnished  
pages\* NONE received by this Authority on \_\_\_\_\_  
pages\* NONE received by this Authority on \_\_\_\_\_

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims <u>1-15</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-15</u>	NO
Industrial Applicability (IA)	Claims <u>1-15</u>	YES
	Claims <u>NONE</u>	NO

**2. Citations and Explanations (Rule 70.7)**

Claims 1-15 lack an inventive step under PCT Article 33(3) as being obvious over US 6,308,737 to Kritiviski. Kritiviski discloses a deformable diverter 80 that serves as a valve body with four ports 100, 200, 300, and 400. Portions of the interior surface of the diverter are selectively contacted through a pinching deformation to isolate ports from one another, creating a flow channel between the two selected ports (see columns 5-7). The ports are configured to be attached to tubing lines 52, 54, 56, and 58 (see FIG 7). According to the illustration in FIG 14, the cross-sectional area between port 300 and port 400 remains substantially constant. With regard to applicant's claim that the valve body is toroidal in shape, the diverter of the Kritiviski device is comprised of an outer and inner surface with a common, empty chamber within the surfaces, rendering the diverter toroidal, with an empty space in the middle, in shape. Nonetheless, absent a showing of the criticality of the cross-sectional area or the toroidal shape to the function of the device, a change in size of a component involves only routine skill in the art. A change in form or shape is generally recognized as being within the level of ordinary skill in the art.

With regard to applicant's claim that the flow channel is cylindrical in cross-section, it would have been an obvious matter of design choice to design the Kritiviski diverter to create a cylindrical cross-section since such a modification would have involved a mere change in the form or shape of a component. A change in form or shape is generally recognized as being within the level of ordinary skill in the art.

With regard to applicant's claims drawn to the tubular portions being pinched of during use, the Kritiviski device does comprise tubular portions in the form of the ports of the diverter. The diverter is pinched in a manner that allows these tubular portions to communicate with or be isolated from one another, depending on the configuration. Applicant's recitation that the tubular portions are pinched during operation of the device amounts to a recitation of the intended use of the invention. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations.

Claims 1-15 meet the criteria set out in PCT Article 33(4), and thus satisfy industrial applicability because the subject matter claimed can be made or used in industry.